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R&D Inc. and Norton (Waterford) Ltd.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL	:	Consolidated Civ. Action No.
	:	20-10172 (JXN) (MAH)
PRODUCTS R&D, INC., and	:	
NORTON (WATERFORD) LTD.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
CIPLA LTD.,	:	
	:	
Defendant.	:	
	:	

PLAINTIFFS TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. AND NORTON (WATERFORD) LTD.'S OPENING POST-TRIAL PROPOSED CONCLUSIONS OF LAW ADDRESSING INFRINGEMENT, OBJECTIVE INDICIA, AND ADMISSIBILITY

Table of Contents

Table of Authorities

Cases

Statutes

Rules

I. Infringement[1]

1. Under 35 U.S.C. § 271(e)(2)(A), whoever submits "an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent" infringes the patent.

2. Under 35 U.S.C. § 271(a), "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."

3. "Literal infringement exists if each of the limitations of the asserted claim(s) read on, that is, are found in, the accused device." *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1583 (Fed. Cir. 1995). If a defendant infringes even one claim, it infringes the patent, *Panduit Corp v. Dennison Mfg. Co.*, 836 F.2d 1329, 1330 n.1 (Fed. Cir. 1987), and the patentee is entitled to a remedy, including all applicable statutory remedies, *see* 35 U.S.C. § 271(e)(4)(A), (B).

4. A proper "infringement analysis entails two steps." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). "The first step is determining the meaning and scope of the patent claims asserted to be infringed." *Id.* "The second step is comparing the properly construed claims to

[1] To the extent any of the followings issues are deemed issues of fact, Teva incorporates such issues into its Proposed Findings of Fact.

the device accused of infringing." *Id.* Thus, a court "must disregard the testimony of [an] expert . . . [if] based on an incorrect understanding of the claim construction." *Cordis Corp. v. Bos. Sci. Corp.*, 658 F.3d 1347, 1357 (Fed. Cir. 2011).

5. "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111 (Fed. Cir. 2004)). Infringement can only be assessed by "comparing the asserted claim[s] to the accused device, not by comparing the accused device to the figures of the asserted patent." *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1286 (Fed. Cir. 2002). It is likewise impermissible to compare the asserted claims "with the patentee's commercial embodiment." *Int'l Visual Corp. v. Crown Metal Mfg. Co.*, 991 F.2d 768, 772 (Fed. Cir. 1993) (per curiam).

6. "Direct infringement is a strict-liability offense." *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 639 (2015) ("[A] defendant's mental state is irrelevant."). Thus, whether the relevant component in the defendant's product has the "purpose" of performing a claim limitation is irrelevant if it performs that limitation. *See, e.g.*, *Toshiba Corp. v. Imation Corp.,* 681 F.3d 1358, 1368-69 (Fed. Cir. 2012) (rejecting argument that accused product did not infringe because accused element did not have the "purpose" of performing the claim limitation); D.E. 217, at 5 (Markman Order) (citing *Toshiba*, 681 F.3d at 1368).

7. Infringement is a question of fact, which a patentee can prove by a preponderance of the evidence (*i.e.*, that it is "more likely than not" that infringement occurred). *See Lucent Techs. Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1309, 1317-18 (Fed. Cir. 2009); *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1341-42 & n.15 (Fed. Cir. 2005); *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1364 (Fed. Cir. 2017. Unlike a defendant who argues that a patent is invalid, a patentee need not satisfy any heightened standard. *See Lucent Techs.*, 580 F.3d at 1317-18.

8. As with other questions of fact, a patentee may prove infringement by direct or circumstantial evidence. *Lucent Techs.*, 580 F.3d at 1318. Direct evidence is not required. *See Symantec Corp. v. Comput. Assocs. Int'l Inc.*, 522 F.3d 1279, 1293 (Fed. Cir. 2008). "A patentee may prove infringement by 'any method of analysis that is probative of the fact of infringement.'" *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009) (quoting *Forest Labs., Inc. v. Abbott Labs.*, 239 F.3d 1305, 1312 (Fed. Cir. 2001)).

9. Nevertheless, factual disputes have their limits; a defendant cannot raise a factual dispute based on its expert's conclusory testimony. *See Intell. Sci. & Tech., Inc. v. Sony Elecs., Inc.,* 589 F.3d 1179, 1184 (Fed. Cir. 2009) ("An expert's unsupported conclusion on the ultimate issue of infringement will not alone create a genuine issue of material fact."); *Arthur A. Collins, Inc. v. N. Telecom Ltd.*, 216 F.3d 1042, 1046 (Fed. Cir. 2000) ("[I]t is well settled that an expert's unsupported conclusion on the ultimate issue of infringement is insufficient to raise a genuine issue of material fact."); *Warner-*

Lambert, 418 F.3d at 1341-42 ("[B]ald assertion" of noninfringement insufficient absent "specific evidence").

10. "It is well settled that an accused device that 'sometimes, but not always, embodies a claim[] nonetheless infringes.'" *Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1333 (Fed. Cir. 2013) (quoting *Bell Commc'ns Res., Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 622-23 (Fed. Cir. 1995)). Thus, "infringement is not avoided merely because a non-infringing mode of operation is possible." *Core Wireless Licensing S.A.R.L. v. Apple Inc.*, 899 F.3d 1356, 1363 (Fed. Cir. 2018) (citing *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1350 (Fed. Cir. 2007); *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1322 (Fed. Cir. 2014)).

11. Under 35 U.S.C. § 271(e)(4)(A), for an act of infringement described in 35 U.S.C. § 271(e)(2)(A), the Court "shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed."

12. Under 35 U.S.C. § 271(e)(4)(B), for an act of infringement described in 35 U.S.C. § 271(e)(2)(A), the Court may grant a permanent injunction "to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug." In addition, under 35 U.S.C. § 283, the Court "may grant injunctions in accordance with the principles of

equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable."

13. Under 35 U.S.C. § 285, a "court in exceptional cases may award reasonable attorney fees to the prevailing party."

14. Under Federal Rule of Civil Procedure 54(d)(1), unless provided "otherwise, costs—other than attorney's fees—should be allowed to the prevailing party."

15. Cipla's submission of Cipla's ANDA infringes the Asserted Claims under 35 U.S.C. § 271(e)(2)(A).

16. The commercial use, manufacture, sale, offer for sale, or importation into the United States of Cipla's ANDA Products would infringe the Asserted Claims under 35 U.S.C. § 271(a).

17. Cipla is not entitled to a declaration and judgment that Cipla does not infringe the Asserted Claims.

18. Teva is entitled to an order, under 35 U.S.C. § 271(e)(4)(A), that the effective date(s) of the U.S. Food & Drug Administration's ("FDA's") approval of Cipla's ANDAs shall be a date not earlier than the latest expiration date of the '289, '587, and '808 Patents, including any adjustments, extensions, or exclusivities.

19. Cipla is not entitled to a declaration and judgment that Cipla has the lawful right to manufacture, import, use, sell, and/or offer to sell Cipla's ANDA Product in the United States following approval from FDA.

20. Teva is entitled to an injunction, under 35 U.S.C. §§ 271(e)(4)(B) and 283, prohibiting Cipla and its officers, agents, servants, and employees from manufacturing, using, offering for sale, selling, or importing into the United States Cipla's ANDA Products prior to the latest expiration date of the '289, '587, and '808 Patents, including any adjustments, extensions, or exclusivities.

21. Cipla is not entitled to an injunction that Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them be preliminarily and permanently enjoined from threatening or initiating litigation alleging infringement of the '289, '587, and '808 Patents against Cipla or any of its customers, dealers, or supplies, or any prospective or present sellers, dealers, distributors, or customers, or charging them, orally or in writing, with infringement of the '289, '587, and '808 Patents.

22. Teva is entitled to an award of attorney's fees under 35 U.S.C. § 285 because this is an exceptional case.

23. Teva is entitled to an award of costs under Federal Rule of Civil Procedure 54(d)(1).

24. Cipla is not entitled to an award of attorney's fees under 35 U.S.C. § 285 because this is an exceptional case.

25. Cipla is not entitled to an award of costs under Federal Rule of Civil Procedure 54(d)(1).

II. Objective Indicia of Nonobviousness

26. In *Graham v. John Deere Co.*, 383 U.S. 1, 17, 35-36 (1966), the Supreme Court recognized that certain objective facts can serve as indicia of nonobviousness and "guard slipping into the use of hindsight." *Apple Inc. v. Samsung Elecs., Co.*, 839 F.3d 1034, 1052 (Fed. Cir. 2016) (en banc). Such objective indicia "may often be the most probative and cogent evidence in the record" and "establish that an invention appearing to have been obvious in light of the prior art was not." *Id.* (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983)).

27. Objective indicia of nonobviousness "must be considered in every case where present." *Apple*, 839 F.3d at 1049. However, the existence of objective indicia is "***not*** a requirement for patentability," and any lack of objective indicia is a "neutral factor." *Custom Assocs., Inc. v. Jeffrey Allan Indus., Inc.*, 807 F.2d 955, 960 (Fed. Cir. 1986) (emphasis added). A court need resolve issues related to objective indicia if the defendant fails to carry its burden on the other elements of obviousness. *Id.*[2] And courts uphold patents even where the patentee adduces no evidence of objective indicia whatsoever. *See, e.g.*, *MobileMedia Ideas LLC v. Apple Inc.*, 780 F.3d 1159, 1165

[2] *See also Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012) ("Because we agree . . . that the Defendants failed to prove that claim 12 of the '528 patent would have been prima facie obvious . . . , we need not address the court's findings regarding objective evidence of nonobviousness."); *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 555 F. App'x 961, 971 (Fed. Cir. 2014) (similar).

(Fed. Cir. 2015) ("MobileMedia did not present evidence of objective indicia of nonobviousness . . .").

28. Relevant objective indicia of nonobviosuness include praise; industry participants are "not likely to praise an obvious advance over the known art." *Apple*, 839 F.3d at 1052. Praise therefore "provides probative and cogent evidence that [a POSA] would not have reasonably expected" the claimed invention. *Institut Pasteur v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013).

29. For evidence of objective indicia to be afforded "substantial weight," a patentee need only prove that it has "a 'nexus' to the claims, *i.e.*, that there is 'a legally and factually sufficient connection" between the evidence and the merits of the patented invention." *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (quote *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988)). To be entitled to some weight, a patented invention need not be "solely responsible" for the objective indicia at issue. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1273 (Fed. Cir. 1991).

30. Nexus is presumed where "the patentee shows that the asserted objective evidence is tied to a specific product and that product 'is the invention disclosed and claimed in the patent.'" *WBIP LLC v. Kohler Co.*, 829 F3d. 1317, 1329 (Fed. Cir. 2016). Under such circumstances, the burden shifts to the defendant to rebut the presumed nexus. *See id.* A defendant "cannot successfully rebut the

presumption with argument alone—it must present evidence." *Id.* (citing *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000)).

31. Pharmaceutical companies "often obtain a package of patents protecting the product," which "may result from continuing improvements in a product or process." *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 730 (Fed. Cir. 2017). Thus, the fact that a patentee (or other entity) owns multiple patents covering the same invention does "not necessarily detract" from the probative value of any objective indicia; which speak "to *the merits of the invention*, not to how many patents are owned by a patentee." *Id.* at 731.

32. A patentee need only prove the existence of objective indicia by a preponderance of the evidence. *See Apple*, 839 F.3d at 1053.

33. Objective evidence of praise supports the nonobviousness of the Asserted Claims of the '289, '587, and '808 Patents.

III. Admissibility

34. Federal Rule of Evidence 401 provides:

> Evidence is relevant if:
>
> (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and
>
> (b) the fact is of consequence in determining the action.

35. Federal Rule of Evidence 402 provides:

> Relevant evidence is admissible unless any of the following provides otherwise:

> the United States Constitution;
>
> a federal statute;
>
> these rules; or
>
> other rules prescribed by the Supreme Court.
>
> Irrelevant evidence is not admissible.

36. Federal Rule of Evidence 403 provides:

> The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.

37. "'Relevant evidence' is defined as that which has 'any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.' The Rule's basic standard of relevance thus is a liberal one." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993) (quoting Fed. R. Evid. 401).

38. If evidence is admissible under Rule 401 and 402, that evidence should be excluded under Rule 403 "only sparingly since the evidence excluded is concededly probative. The balance of the rule should be struck in favor of admissibility." *Blancha v. Raymark Indus.,* 972 F.2d 507, 516 (3d Cir.1992); *Suter v. Gen. Acc. Ins. Co. of Am.*, 424 F. Supp. 2d 781, 790 (D.N.J. 2006).

39. Courts have "recognized that in the context of a bench trial, evidence should not be excluded under Rule 403 on the grounds that it is unfairly prejudicial,

because the Court is capable of assessing the probative value of the article and excluding any arguably improper inferences." *Suter*, 424 F. Supp. 2d at 790 (quoting *Tracinda Corp. v. DaimlerChrysler AG,* 362 F. Supp. 2d 487, 497 (D. Del. 2005)).

40. Federal Rule of Evidence 701 provides:

> If a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that is:
>
> (a) rationally based on the witness's perception;
>
> (b) helpful to clearly understanding the witness's testimony or to determining a fact in issue; and
>
> (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.

41. Federal Rule of Evidence 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

42. Under Third Circuit law, "a lay witness' opinion on technical matters may be admissible if it 'derive[s] from a sufficiently qualified source as to be reliable and hence helpful to the [finder of fact].'" *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 237

F.R.D. 106, 114-15 (D. Del. 2006) (quoting *Asplundh Mfg. Div. v. Benton Harbor Eng'g,* 57 F.3d 1190, 1201 (3d Cir. 1995)); *Magnetar Techs. Corp. v. Six Flags Theme Parks Inc.*, No. 07-127-LPS-MPT, 2014 WL 530241, at *9 (D. Del. Feb. 7, 2014).

43. "[T]he modern trend favors the admission of [fact] opinion testimony, provided that it is well founded on personal knowledge and susceptible to specific cross-examination.'" *Ghee v. Marten Transp., Ltd.*, 570 F. App'x 228, 231 (3d Cir. 2014) (quoting *Lightning Lube, Inc. v. Witco Corp.,* 4 F.3d 1153, 1175 (3d Cir. 1993)); *Teen-Ed, Inc. v. Kimball Int'l, Inc.,* 620 F.2d 399, 403 (3d Cir. 1980)).

44. That a fact witness "may have been able to qualify as an expert witness" does not "prevent" that testimony provided that it satisfies the requisite standards. *Ricci v. Caring, Inc.*, No. 02-3468-JHR, 2005 WL 8174769, at *2 (D.N.J. Oct. 31, 2005) (citing *Asplundh Mfg.*, 57 F.3d at 1198; *Teen-Ed*, 620 F.2d at 403).

45. Accordingly, courts in patent cases routinely permit fact witnesses to testify about the functioning of the devices at issue. *See, e.g.*, *Braun Corp. v. Maxon Lift Corp.*, 282 F. Supp. 2d 931, 934 (N.D. Ind. 2003) (admitting fact witness declaration regarding patented invention and accused product), *aff'd*, 97 F. App'x 335 (Fed. Cir. 2004); *Hynix Semiconductor Inc. v. Rambus Inc.*, No. 00-20905 RMW, 2009 WL 230039, at *10 (N.D. Cal. Jan. 27, 2009) ("[T]he court does not believe it is 'expert' testimony for an inventor to explain the process by which he made his discoveries, for an engineer to describe the products he has built, or for a scientist to explain what he knew at a certain point in time.").

46. Teva's proffered Submission of Aurobindo Deposition Testimony, Associated Exhibits, and Test Videos (D.E. 234, 234-1) should be admitted.

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Respectfully submitted,

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